Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/025R Issued: 12 July 2018 Valid until: July 2019

Novaline haemodialysis bloodlines used with Baxter/Gambro haemodialysis machines – Recall of specific products due to various problems encountered during clinical use

Summary

Manufactured by Vital Healthcare Sdn for distribution by Baxter Healthcare Ltd – specific product codes manufactured in 2017 have functional and assembly issues which may lead to air entering the system, blood loss, clotting and delays in treatment

Action

- Quarantine and return affected bloodlines
- Identify appropriate alternatives
- If suitable alternatives are not available, you should:
    - undertake a local risk assessment prior to using the affected devices
    - ensure users are aware of the seven problems listed within the FSN and are able to carry out the additional monitoring checks for each problem
- Ensure users continue to undertake checks for the problems listed in the Background section once redesigned 2018 models of Novaline bloodlines are in use.
- Share this information with home patients and satellite clinics who have been supplied with the affected products

Action by
Renal unit nurses and renal technicians.

Deadlines for actions
Actions underway: 08 August 2018
Actions complete: 05 September 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru
Welsh Government

Device details

The bloodlines are manufactured by Vital Healthcare Sdn Bhd, for distribution by Baxter International Inc (Baxter Healthcare Ltd in UK).
The bloodlines are used with Baxter/Gambro haemodialysis machines – see table below for machines that use the specific codes affected by the FSCA:

Model of dialysis bloodline	Product Code	NDC code (Scotland)	Used with Baxter/Gambro haemodialysis machine
BL 106	955443		Baxter AK 95 S, AK 96, AK 98, AK 200 S & AK 200 ULTRA S
BL 224	955446		Baxter AK 200 S and AK 200 ULTRA S
BL 24	955307		Baxter AK 95 S, AK 96, AK 98, AK 200 S
BL 208	955445		Baxter AK 200 S and AK 200 ULTRA S
BL 207	955448		Baxter AK 96, AK 98, AK 200 S, AK 200 ULTRA S
BL 211 SN	955447		Baxter AK 200 S, AK 200 ULTRA S
BL 148 SN	955305		Baxter AK 200 S, AK 200 ULTRA S
BL200 HDF	955444	223978	Baxter AK 200 ULTRA S
BL 10R	955300		Baxter AK 95 S, AK 96, AK 98, AK 200 & AK 200 ULTRA
BL 245	955449	222896	Baxter AK 95 S, AK 96, AK 98, AK 200 S & AK 200 ULTRA S

Background

Although the manufacturer has undertaken corrective actions to address some of the problems identified in the FSN, some ongoing checks are required when using the redesigned bloodlines.

User checks for the following problems should be taken when using all models and manufacture dates of Novaline bloodlines:

Problem	Risk	Action
Blood pump on the machine does not stop when blood reaches the venous extracorporeal blood circuit.	Blood loss.	Operator to check that the blood pump stops when blood reaches the venous drip chamber. If the operator recognises that the pump may not stop, operator should stop the blood pump manually and then connect the patient.
Transducer protectors not connected properly	Air entrance into the circuit	Operator to check connections as per section 5.4 of IFU
Rare events of improper or incorrect fitting between arterial chamber and machine holders	Risk of air within the arterial chamber entering the bloodline circuit.	Operator must check that the arterial chamber is placed at the right hole of the holder suiting its size and is properly fitted in.

Manufacturer contacts

Distributor – Baxter Healthcare Ltd.
Gerard Spicer
Tel: 01604 704665
Email: gerard_spicer@baxter.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including: A&E consultants

- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Clinical perfusionists
- Community hospitals
- Haemodialysis nurses
- Haemodialysis units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Peritoneal dialysis units
- Purchasing managers
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Satellite dialysis units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers

Public Health England

Directors for onward distribution to:

- Risk manager
- Safety officers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/025R** or **2018/005/002/601/001**.

Technical aspects
Roopa Prabhakar or Jonathan Fox, MHRA

Tel: 020 3080 7293 / 020 3080 7030

Email: roopa.prabhakar@mhra.gov.uk or jonathan.fox@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care
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